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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,079	02/16/2000	Gail M. Clinton	49321-1A	5713

7590 06/14/2006

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/506,079	CLINTON ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8-10,18-20 and 38-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8-10,18-20 and 38-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The response the restriction requirement mailed 10/27/2005 is acknowledged. Upon further consideration, the restriction requirement is WITHDRAWN.

Claims 1-3, 8-10, 18-20 and 38-49 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections Withdrawn:

3. The objection to the specification for failing to comply with the sequence rules set forth in 37 CFR 1.821 through 1.825 is withdrawn in view of the new sequence listing (CRF and paper copy) that was filed 1/18.2005.

4. The rejection of claims 1-3, 8-10, 18-20 and 38-41 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendment removing the negative limitation.

5. The rejection of claims 1-3, 8-10, 18-20 and 38-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment

and further in view of the declaration filed by Gail Clinton (filed under 37 C.F.R. 1.132 on 1/18/2005) demonstrating that three variants have biological activity, and also applicants' arguments that a demonstration of activity in more than one variant should be sufficient to enable the genus.

New Grounds of Rejection:

6. Claims 8-10, 18, 40, 41, and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that claims with recitations concerning the number of glycosylation sites introduce new matter into the specification.

Claims 8, 10, 18, 40, 41, 46 and 48 are drawn to isolated polypeptides comprising an amino acid sequence of SEQ ID NOS: 15, 29-38 and fragments thereof, wherein the isolated polypeptide is from about 80-419 contiguous residues in length, and at least one N-linked glycosylation site is present. Claims 9 and 47 are drawn to isolated polypeptides comprising an amino acid sequence of SEQ ID NOS: 15, 29-38 and fragments thereof, wherein the isolated polypeptide is from about 350-419 contiguous residues in length, and at least three N-linked glycosylation sites are present.

These claims were not originally presented at time of filing, and in the amendment that presented these claims, applicant failed to indicate where in the specification or original claims support could be found for the amendment. Furthermore, an inspection of the specification

shows that what was originally claimed was isolated and glycosylated polypeptides comprising the amino acid sequence of SEQ ID NO: 2 (SEQ ID NO: 2 encompasses SEQ ID NOS: 15 and 29-38) or fragments thereof, wherein the isolated polypeptide is from about 80-419 contiguous residues in length, and has at least *three* N-linked glycosylation sites; or wherein the isolated polypeptide is from about 350-419 contiguous residues in length, and has at least *four* N-linked glycosylation sites. Therefore, the change from what was originally filed appears to be the minimum number of N-linked glycosylation sites present in the claimed isolated and glycosylated polypeptides. This change in number of glycosylation sites introduces new matter into the specification, because there is no written support found for the newly claimed isolated and glycosylated polypeptides. Therefore, it appears that applicants were not in possession of the claimed inventions at the time the application was filed.

7. Claims 1-3, 8, 10, 18, 19, 40, 42-44, 46 and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Doherty (Proc. Natl. Acad. Sci., USA, 96: 10869-10874, 1999, September; of record).

Claims 1-3, 8, 10, 18, 19, 40, 42-44, 46 and 48 do not receive benefit of priority to the parent application, 09/234,208, because SEQ ID NOS: 14, 15 and 19-38 are not found in the parent application. Therefore, the filing date of the instant application is used for comparison with the prior art (2/16/2000).

The claimed polypeptides and pharmaceutical compositions are drawn to products comprising *an* amino acid sequence selected from the group consisting of SEQ ID NOS: 14, 19-28, and fragments thereof of about 50 – 79 contiguous residues in length, where the polypeptide

binds to the extracellular domain of Her-2 with an affinity binding constant of at least 10^8 M^{-1}; or comprising *an* amino acid sequence selected from the group consisting of SEQ ID NOS: 15, 29-38, and fragments thereof of about 80 – 419 contiguous residues in length, where the polypeptide binds to the extracellular domain of Her-2 with an affinity binding constant of at least 10^8 M^{-1}. Because of the recitation "comprising *an* amino acid sequence", the claimed polypeptides encompass polypeptides comprising subsequences of SEQ ID NOS: 14, 19-28, and of SEQ ID NOS: 15, 29-38. In the case of claims 44 and 48, which lack the phrase "amino acid sequence of", the limitation of the independent claims from which clams 44 and 48 depend (claims 42 and 46) are applied to these claims. The claims to pharmaceutical compositions are interpreted to read on the polypeptide products, with the phrase "pharmaceutical composition" interpreted as an intended use recitation.

Doherty teaches a polypeptide that comprises a subsequence of any of SEQ ID NOS: 14, 15 and 19-38 (see page 10870, Figure 1). Therefore, Doherty teaches the polypeptides and pharmaceutical compositions as claimed. This rejection would be overcome by amending the claims to recite "polypeptide comprising *the* amino acid sequence selected from the group consisting of...".

8. Claims 38, 39, 45 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Chemical Company (Sigma Chemical Company Catalogy, 1989, pages 914, 918, 1171, and 1243).

The claims are drawn to isolated polypeptides consisting of an amino acid sequence selected from the group consisting of SEQ ID NOS: 14, and 19-28; consisting of the group SEQ

ID NOS: 15 and 29-38; or SEQ ID NO: 14; or SEQ ID NO: 15. Because of the recitation "consisting of an amino acid sequence", the claims read on subsequences such as dipeptides.

The Sigma Chemical Company sells dipeptides such as Leu-Arg, Leu-Pro, Phe-Tyr, and Pro-Gly, which are all subsequences in SEQ ID NO: 14 or SEQ ID NO: 15. Therefore, the Sigma Chemical Company sells dipeptides that are within the scope of the claimed peptides.

9. Claims 1-3, 8-10, 18-20, 40-44, 46-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Doherty (U.S. 6,414,130; published Jul. 2, 2002; effective filing date Jan. 20, 1999; of record)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Doherty discloses SEQ ID NO: 1 and SEQ ID NO: 2, which are the amino acid sequences of polypeptides that comprise subsequences of any of SEQ ID NOS: 14, 15, and 19-38. Thus, Doherty teaches polypeptides that are the same as that claimed. This rejection would be overcome by amending the claims to recite "polypeptide comprising *the* amino acid sequence selected from the group consisting of...".

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
June 9, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Clinton et al.
Filing Date: 16 February 2000
Serial No.: 09/506,079
For: HER-2 BINDING ANTAGONISTS
Art Unit: 1642
Examiner: Anne L. Holleran
Docket: 49321-16
Date: 28 January 2005

Considered AUH 6/9/06

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT OF DR. GAIL M. CLINTON UNDER 37 C.F.R. § 1.132
(IN SUPPORT OF RESPONSE AND AMENDMENT UNDER37 CFR § 1.111)

Sir or Madam:

I, Dr. Gail Clinton, being duly sworn, say:

1. I am an inventor of the subject matter described in the above-identified pending patent application.

2. I am presently employed as an Associate Professor at Oregon Health and Science University in Portland, Oregon (from 1/01/87 to present). I received a Bachelor of Science Degree in 1969 from the University of California, San Diego, and a Ph.D. degree from the University of California, San Diego in 1974. I completed a postdoctoral fellowship at Harvard Medical School in 1981.

3. I am an author or co-author of more than 50 peer-reviewed research articles in the field of oncogene regulation and I am a member of a number of scientific and medical societies, most notably American Association of Cancer Research. I have received a number of prizes and